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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,146	03/17/2004	Nancy Jean Britten	PC027932A	5036

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
01/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,146	BRITTEN ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-27 and 33-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-27 and 33-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments filed November 4, 2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 25-27 and 33-58 are pending in this application.

Terminal Disclaimer

The terminal disclaimers filed on November 4, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 12/037556 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 25-27 and 33-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patil et al. U.S. Patent No. 4,299,501 and Ranbaxy Laboratories LTD. (hereinafter referred to as Ranbaxy) WO 02/17923.

Patil et al. teach a composition comprising peglicol-5-oleate (A), microcrystalline wax (B) (see example 4, column 4) mineral oil (C) (column 3, lines 53-54; column 4,

lines 44-45) along with an emulsifier (as in instant claim 57) (column 3, lines 3-15). The composition included other ingredients such as pharmaceutical materials (column 3, lines 8-9). Ranbaxy teach topical delivery of cyclooxygenase-2 (COX-2) enzyme inhibitors (page 4, lines 16-18), such as celecoxib, valdecoxib, rofecoxib, varecoxib, parecoxib and the like (page 6 line 21 to page 7, line 2). It would have been obvious to one having ordinary skill in the art to substitute any of the COX-2 enzyme inhibitors of Ranbaxy for the "pharmaceutical material" of Patil et al. to arrive at a pharmaceutical composition comprising the amphipathic oil (peglicol-5-oleate), a non-aqueous carrier (mineral oil) and microcrystalline wax. The prior art does not teach the amphipathic oil that is water dispersible and ethanol insoluble, and is a polyglycolized glyceride that is prepared by an alcoholosis reaction of natural triglycerides with polyethylene glycol, however, claim instant claim 58 indicates that all of these properties are contained in the peglicol 5-oleate and as such, the characterization described in instant claims 25-27 and 33-58 are obvious over the peglicol 5-oleate of Patil et al.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed; however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed

invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Regarding the dosages instantly claimed, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe inflammation would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. For these and other self-evident reasons, it would have been obvious to have used dosages of COX-2 inhibitors in a concentration of 0.01 to 1000 mg/ml

Further, regarding the amounts of amphipathic oil, microcrystalline wax and non-aqueous carrier, the specific safe and effective amount will be vary, with such factors as the particular COX-2 inhibitor being dispersed into the composition, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. It would have been obvious to vary the amounts of amphipathic oil, microcrystalline wax and non-aqueous carrier. Regarding instant claim 51, 52 and 58, drawn to inter alia, cottonseed oil, Patil et al. teach mineral oil as a non-aqueous carrier. It would have been prima facie obvious to substitute one non-aqueous carrier for the other. Express suggestion to substitute one equivalent for

another need not be present to render such substitution obvious. Patil et al. showed that the amphipathic oil, peglicol 5-oleate combined with the nonaqueous carrier mineral oil and microcrystalline wax is an effective carrier for pharmaceutical material and Ranbaxy showed that COX-2 enzyme inhibitors are effective when administered topically. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the carrier taught in Patil et al for the carrier of Ranbaxy for the predictable result of forming a stable composition for administration of COX-2 inhibitors, such as celecoxib

Response to Arguments

Applicant asserts that the only use which Patil et al. suggest for the oil phase of their composition is to be mixed with a water phase and forced through a system of mixers and homogenizers until a suitable emulsion is formed. In response, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts. As such, it does not exclude water dispersed in the composition. Applicant is in disagreement with the Examiner regarding the Patil et al. reference because "if the carrier of Patil et al. is substituted for the carrier or Ranbaxy, the person skilled in the art would have a drug in a water containing emulsion and not Applicant's oil based composition, and Applicant further asserts that because a person skilled in the art would not be motivated to use the oil phase of Patil et al. as a carrier because Patil et al. provide only one use for this oil phase, to be mixed with an aqueous phase and homogenized to form an emulsion". In response, the claims are drawn to a

pharmaceutical composition comprising a vehicle that comprises (a) amphipathic oil that is water dispersible (b) microcrystalline wax and (c) a non aqueous carrier. The claims do not teach water, however the broad claim language "comprising" does not exclude the possibility of the addition of water. The instant specification also teach the pharmaceutical composition in a "dispersed phase" as an emulsion or suspension (see page 14, lines 26-31).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-

0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

January 7, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614